ALARA INCORPORATED

K032210

OCT - 2 2003

F. 510(k) Summary

CrystalView™ Computed Radiography System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: Alara, Inc.
2545 Barrington Court
Hayward, CA 94545

Contact Person: Diane M. King
VP Regulatory Affairs
Phone: 510-265-6224
Fax: 510-723-0111

Date Prepared: July 18, 2003

Trade Name: CRystalView Computed Radiography System

Common Name: Computed Radiography (CR) System

Classification Name: Solid State X-Ray Imager (per 21 CFR 892.1650)

Predicate Device: PhorMax Eagle Scanner 510(k) # K001499
Agfa ADC Compact K974597

Product Description:

The Alara CRystalView™ is a Desktop Computed Radiography (CR) System designed to generate digital x-ray images by scanning photo-stimulable storage phosphor imaging plates exposed using standard X-ray systems and techniques. The system consists of a CR Reader, a QC workstation with software, cassettes, and imaging plates. Image data is sent via a dedicated connection from the Reader to the CRystalView QC Workstation, where it is processed and displayed for review. The system outputs images and patient information to a PACS using the standard DICOM 3.0 protocol. The fully configured CRystalView System includes acquisition console software and post-processing image enhancement software. A reseller may alternatively provide these two software components or appropriately cleared equivalents, as well as the QC Workstation hardware.

Indications for Use:

CRystalView is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

Rationale for Substantial Equivalence

CRystalView has the same or similar indications for use as the predicate devices. CRystalView shares the same technological characteristics as the predicate devices. However, the descriptive characteristics are not sufficiently precise to assure substantial equivalence. Therefore, Alara has carried out validation and image quality performance testing, including a clinical concurrence study. The results of this testing demonstrate that CRystalView is substantially equivalent to the predicate devices.

Safety and Effectiveness Information:

CRystalView is a Class II medical device, and a Class I laser product. CRystalView complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and laser safety of medical and/or laser devices.

Alara has performed laboratory and clinical studies to demonstrate CRystalView performance characteristics and equivalent diagnostic capabilities as the predicate. The results of these studies show that CRystalView performance characteristics are comparable with those of the predicate devices. Clinically, no statistically significant difference was found in image quality ratings of CRystalView and the Agfa ADC Compact when images were judged by a radiologist.

Conclusion:

CRystalView performance tests and clinical studies have demonstrated that CRystalView is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Ms. Diane M. King
VP, Regulatory Affairs
Alara, Inc.
2545 Barrington Court
HAYWARD CA 64545

Re: K032210
Trade/Device Name: Alara CRystalView™ Computed Radiograph System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: July 18, 2003
Received: July 21, 2003

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

E. Statement of Indications for Use

510(k) Number (if known): K032210

Device Name: Alara CRystalView™ Computed Radiography System

Indications for Use: CRystalView is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032210

(Optional Format 3-10-98)